6 MEDICAL SCREENING AND SURVEILLANCE

6.1 OBJECTIVES OF MEDICAL SCREENING AND SURVEILLANCE

The REL of 1 mg/m^3 for respirable coal mine dust does not assure a zero risk for the development of occupational respiratory diseases among all miners exposed during a full working lifetime. Consequently, a medical screening and surveillance program that includes initial and periodic chest X-rays and spirometric examinations is important for the early detection of disease and the prevention of "material impairment of health or functional capacity" [30 USC 811(a)(6)(A)]. The medical screening and surveillance program is also useful for disease surveillance, which includes the tracking trends, the setting of prevention and intervention priorities, and the assessment of prevention and intervention efforts. NIOSH encourages both underground and surface coal miners to participate in the medical screening and surveillance program.

6.1.1 Definitions

Medical screening is "the application of an examination, historical question, or laboratory test to apparently healthy persons with the goal of detecting absorption of intoxicants or early pathology before the worker would normally seek clinical care for symptomatic disease" [Halperin et al. 1986]. In contrast, medical surveillance involves the evaluation of a population's health status through the periodic collection, analysis, and reporting of data for the purpose of disease prevention [Halperin and Baker 1992]. Medical surveillance data are useful for evaluating the effectiveness of disease prevention and intervention programs. Primary prevention of work-related disease depends on the effective control of worker exposures below occupational exposure limits. Secondary prevention measures include medical screening for the early detection of diseases and medical intervention, which is aimed at reversing or impeding progression of disease.

6.1.2 Criteria for Medical Screening and Surveillance Tests

Acceptable performance of a medical screening test depends on the prevalence of disease in the population as well as the risk of toxicity and the consequences of false positive test results [Matte et al. 1990]. Additional criteria for effective medical screening tests and programs include the following [Weeks et al. 1991; Levy and Halperin 1988]:

- The screening test must have acceptable sensitivity, specificity, and predictive value.
- The screening test must be valid and reliable.
- The screening test must identify disease early and lead to treatment that impedes disease progression.

- Adequate followup, further diagnostic tests, and effective management of the disease must be available, accessible, and acceptable.

- Benefits of the screening program must outweigh the costs.

If a medical screening test indicates the presence of a disease or the increased probability of the presence of disease, further evaluation and diagnostic testing are needed.

NIOSH believes that the tests recommended in the medical screening and surveillance program for coal miners (i.e., chest X-rays and spirometry) reasonably fulfill the criteria for effective screening tests. These recommended tests are performed using standardized methods for administering them and interpreting results. They represent the best available methods for detecting occupation-related respiratory diseases among coal miners. In addition to the medical screening function, the recommended tests are also important for medical surveillance. The characteristics of medical tests used in disease surveillance of a population may differ from those required for the clinical evaluations of individuals [Weeks et al. 1991; Silverstein 1990].

6.2 CURRENT MEDICAL SURVEILLANCE PROGRAM AND RECOMMENDED REVISIONS

6.2.1. Current Chest X-Ray Program

The Coal Workers' X-Ray Surveillance Program was established under the Federal Coal Mine Health and Safety Act of 1969 (P.L. 91-173), which was amended by the Federal Mine Safety and Health Act of 1977 [30 USC 843]. The specifications for giving, interpreting, classifying, and submitting chest X-rays for underground coal miners are provided in 42 CFR 37. Currently, mandatory X-rays include the following:

- An initial chest X-ray within 6 months of beginning employment

- Another chest X-ray 3 years after the initial examination

- A third chest X-ray 2 years following the second one if a miner is still engaged in underground coal mining and if the second chest X-ray shows evidence of category 1 or higher pneumoconiosis according to the ILO classification [ILO 1980]

In addition to these mandatory chest X-rays, mine operators are required to offer an opportunity for periodic, voluntary chest X-rays approximately every 5 years. These chest X-rays must be interpreted by approved, qualified readers [42 CFR Part 37]. Radiographic findings of simple CWP or PMF are reported to MSHA by NIOSH and to the miners by MSHA. All chest X-rays given under the Coal Workers' X-Ray Surveillance Program are submitted to and become the property of NIOSH. Operators of underground coal mines are required to provide chest X-rays at a convenient time and place for all miners who work in underground coal mines or in surface areas of underground coal mines [42 CFR Part 37].

6.2.2 Spirometry Recommendations

The Federal Coal Mine Safety and Health Act of 1977 specifies that the chest X-rays are to be supplemented by "such other tests as the Secretary of Health and Human Services deems necessary" [30 USC 843(a)]. The definition of pneumoconiosis was modified in the Black Lung Benefits Reform Act of 1977 as a chronic dust disease of the lung and its sequelae, including respiratory and pulmonary impairments arising out of "coal mine employment" [30 USC 902(b)]. NIOSH therefore recommends that spirometric examinations be included in the medical screening and surveillance program for coal miners based on

— the definition of pneumoconiosis in the Black Lung Benefits Reform Act of 1977 (which includes respiratory and pulmonary impairments that might not be detected on a chest X-ray but would be detected with spirometry), and

— the evidence (see Chapters 4 and 7) that coal miners can develop COPD from their exposures to respirable coal mine dust—even without radiographic evidence of simple CWP and apart from the effects of cigarette smoking.

The recommended schedule for spirometric examinations is provided in Section 6.3.

6.2.3 Recommendations for Surface Coal Miners

NIOSH also recommends inclusion of surface coal miners in the medical screening and surveillance program based on the evidence (see Chapters 4 and 7) that these miners can develop simple CWP, PMF, silicosis, and decrements in lung function as a result of their exposures to respirable coal mine dust and respirable crystalline silica.

6.2.4 Current and Recommended Option to Work in a Low-Dust Environment

Currently, any miner who shows evidence of the development of pneumoconiosis based on the chest X-ray or other medical examinations has the option to work in a low-dust environment in the mine where the concentration of respirable coal mine dust is not more than 1.0 mg/m^3—or where the concentration is the lowest attainable below 2.0 mg/m^3 if the 1.0 mg/m^3 concentration is not attainable in the mine where the miner works [30 USC 843(b)]. If it is necessary for the miner to transfer to another position in the mine to reduce exposure, the transfer is offered without loss of pay. These miners also receive periodic personal exposure monitoring [30 CFR 90].

The current regulations [30 CFR 90] include only underground coal miners and workers at surface work areas of underground coal mines. NIOSH recommends that the regulations governing eligibility and procedures for the transfer option be amended to include both surface and underground coal miners with radiographic evidence of pneumoconiosis or with confirmed finding of a chronic airways disease based on spirometry and other medical examinations or tests deemed necessary by a licensed physician. NIOSH believes that affording miners with evidence of occupation-related respiratory disease the opportunity to work in a low-dust environment is consistent with the intent of the Americans with Disabilities Act of 1990 [42 USC 10227-13643].

6.3 RECOMMENDED MEDICAL SCREENING AND SURVEILLANCE PROGRAM FOR UNDERGROUND AND SURFACE COAL MINERS

This document refers to the recommended revisions to the Coal Workers' X-Ray Surveillance Program as the "Coal Workers' Medical Screening and Surveillance Program" to better reflect the functions of the program. The recommended preplacement and periodic medical examinations include the following:

- An initial (preplacement) spirometric examination and chest X-ray as soon as possible after beginning employment (within 3 months for a spirometric examination and within 3 to 6 months for a chest X-ray)
- A spirometric examination each year for the first 3 years after beginning employment and every 2 to 3 years thereafter if the miner is still engaged in coal mining
- A chest X-ray every 4 to 5 years for the first 15 years of employment and every 3 years thereafter if the miner is still engaged in coal mining
- A chest X-ray and spirometric examination when employment ends if more than 6 months have passed since the last examination
- A standardized respiratory symptom questionnaire—such as the American Thoracic Society (ATS) respiratory questionnaire [Ferris 1978 (or the most current equivalent)]—to be administered at the preplacement examination and updated at each periodic examination
- A standardized occupational history questionnaire (including a listing of all jobs held up to and including present employment, a description of all duties and potential exposures, and a description of all protective equipment the miner has used or may be required to use) to be administered at the preplacement examination and updated at each periodic examination

6.3.1 Worker Participation

Miners should be provided with information about the purposes of the medical screening and surveillance program, the health-protection benefits of participation, and a description of the procedural aspects of the program. This information should include how screening test results are used, what actions may be taken based on screening results, who has access to screening test results, and how confidentiality is maintained [Matte et al. 1990]. The initial examination (which is currently mandatory) is important for providing baseline values for individuals. Comparing test results for an individual (including baseline values) may indicate a clinically important change that would not be apparent from comparing an individual's results with group reference values. The reason is that normal variation in test results among healthy group members is generally greater than test-to-test variation in individuals [Hankinson and Wagner 1993; Matte et al. 1990]. The fact that periodic examinations are voluntary may improve the reliability of data based on questionnaires and medical tests requiring worker cooperation. Each miner should sign a consent form indicating that he or she has been informed about the purposes of the medical screening and surveillance program and accepts or declines participation. Miners should not suffer consequences because of their choices for or against participation. Recent improvements in the Coal Workers'

X-Ray Surveillance Program (including increased education and communication) have resulted in an encouraging increase in the voluntary participation of coal miners [Wagner et al. 1993a].

6.3.2 NIOSH-Approved Facilities

NIOSH recommends that each mine operator make arrangements with a local NIOSH-approved facility or organization to conduct the medical examinations. The local examination facility or organization should transmit to NIOSH all chest X-rays, pulmonary function test results (including spirograms), completed medical questionnaires, and work histories. NIOSH shall evaluate the technical quality of the chest X-rays and interpret them. In addition, NIOSH shall do the following:

- Evaluate the results of spirometric examinations, completed medical questionnaires, and work histories
- Prepare letters to notify miners of the examination results and to recommend any followup examinations
- Permanently store the medical and questionnaire data

6.3.3 Smoking

NIOSH recommends that the mine operator prohibit smoking and strictly enforce this policy in all underground and surface coal mines and in all other work areas associated with coal mining. The mine operator or the physician should counsel tobacco-smoking miners about their increased risk of developing lung cancer and COPD; the mine operator or physician should also counsel such miners to participate in a smoking cessation program.

6.4 INTERPRETATION OF MEDICAL SCREENING EXAMINATIONS

6.4.1 Evidence of Pneumoconiosis on Chest X-Rays

NIOSH recommends that chest X-rays be classified according to the 1980 ILO Classification of Radiographs of Pneumoconioses (or the most current equivalent) [42 CFR 37 (1989)]. Evidence of pneumoconiosis is present when the chest X-ray is classified as ILO category 1/0 or greater or when large shadows are recorded as likely to be due to PMF or complicated CWP. NIOSH considers two physicians to be in agreement when their classifications meet one of the following criteria:

- They each find complicated pneumoconiosis of any category.
- Their findings with regard to simple pneumoconiosis are both in the same major category.
- Their findings are within one minor category (ILO category 12-point scale) of each other. In this case, the higher of the two interpretations should be reported. The only exception to this criterion is a reading sequence of 0/1, 1/0, or 1/0, 0/1. Such a sequence is not considered agreement, and additional classifications are required until the readers reach a consensus involving two or more readings in the same major category.

6.4.2 Evaluation of Spirometric Examinations

NIOSH recommends that the results of spirometric examinations be evaluated as follows:

- Use the highest FEV_1 and FVC values from each miner's examination when comparing the FEV_1, FVC, and $FEV_1/FVC\%$* with the lower limit of normal (LLN)†.

- Compute the miner's decline in FEV_1 by comparing his or her FEV_1 values over a period of time; a decline of 15% or greater (adjusted for the expected interval decline in FEV_1) is considered significant and warrants further medical evaluation [Hankinson and Wagner 1993; ATS 1991].

A spirometric examination should be repeated within 3 months if it is unacceptable according to ATS criteria [ATS 1991].

Evidence of impaired lung function is present when there is a confirmed finding (based on two or more spirometric examinations) of either of the following:

- The FEV_1, FVC, or FEV_1/FVC value from an acceptable test is below the LLN (Knudson et al. [1983] and Appendix E, or the most current equivalent).

- A decline in FEV_1 (adjusted for the expected interval decline in FEV_1) is 15% or greater [Hankinson and Wagner 1993; ATS 1991].

6.4.3 Worker Notification

Workers should be notified in a timely manner regarding the results of their medical examinations, including whether or not any abnormalities were detected. A NIOSH contact person should be provided for further information.

When a miner first shows evidence of impaired lung function based on the results of the spirometric examination (Section 6.4.2), he or she should be notified that the spirometric examination should be repeated within 3 months.

Any miner with either radiographic evidence of pneumoconiosis (as described in Section 6.4.1) or a confirmed finding of impaired lung function (as described in Section 6.4.2) should be notified of his or her option to work in an environment where the exposures are as far as feasible below the RELs for respirable coal mine dust and respirable crystalline silica. In addition, the miner should be advised to consult a licensed physician or other qualified health care provider regarding appropriate medical followup and intervention measures, which may include those listed in Section 6.4.4.

*The ratio of FEV_1/FVC is conventionally expressed as a percentage. The miner's highest FEV_1 and FVC values are used to compute this ratio.

†The LLN is calculated with the equations published by Knudson et al. [1983] (Appendix E) or the most current equivalent. See Section 6.5.4 for a discussion of the LLN.

6.4.4 Medical Followup and Intervention

Medical followup and intervention that should be considered by the physician and the miner include the following measures:

- Further medical examination and testing determined by and performed by or under the direction of a licensed physician
- Annual spirometric examination
- Participation in a smoking-cessation program, if applicable
- The option to work in an environment with exposures as far as feasible below the RELs for respirable coal mine dust and respirable crystalline silica

6.5 LUNG FUNCTION TESTS FOR MEDICAL SCREENING AND SURVEILLANCE

Spirometry is the most important test for evaluating a miner's lung function [Attfield and Wagner 1992b]. The most widely accepted spirometry tests for screening workers are those for FEV_1 and FVC [Hankinson 1986]. The detection of lung function values below normal reference values or the detection of a significant decline in lung function over time indicates that further examination and testing are needed to confirm the test results, to determine the cause(s) of the reduced lung function, and to identify appropriate intervention or therapeutic measures.

6.5.1 Determining Obstructive and Restrictive Ventilatory Defects

Obstructive and restrictive ventilatory defects are two basic disease patterns detected by spirometry. An obstructive ventilatory defect indicates airflow limitation caused by airway narrowing during expiration [ATS 1991]. A greater reduction in FEV_1 than in VC (i.e., FEV_1/FVC decreased) suggests an obstructive ventilatory defect [ATS 1991]. Diseases associated with this pattern include asthma, chronic bronchitis, and emphysema [Garay 1992].

Reduced VC and normal or increased FEV_1/FVC suggest a restrictive ventilatory defect [ATS 1991]. Pneumoconiosis and other interstitial lung diseases can cause restrictive ventilatory defects. Exposure to respirable coal mine dust may cause obstructive, restrictive, or mixed ventilatory defects.

FEV_1 is ideal as a screening tool because it detects ventilatory defects reflecting either restrictive or obstructive patterns. However, FEV_1 should not be used without the FEV_1/FVC[‡] ratio to distinguish between disease patterns because FEV_1 may be decreased in both the obstructive and restrictive patterns, as shown here:

[‡]FVC may be lower than VC in persons with airways obstruction because of gas trapping; thus, the ratio of FEV_1/FVC appears to be more normal than the ratio of FEV_1/VC. For this reason, the ATS recommends using FEV_1/VC to determine the ventilatory disease pattern [ATS 1991]. However, FVC is used for screening because it is easily obtained when measuring FEV_1.

Obstructive pattern	*Restrictive pattern*
FVC normal or slightly decreased	FVC decreased
FEV_1 decreased	FEV_1 decreased
FEV_1/FVC decreased	FEV_1/FVC normal or slightly increased

Determining the disease pattern is more relevant to clinical diagnosis and treatment than to workplace spirometry screening, where early identification of a ventilatory defect is the primary ojective.

Once a ventilatory defect is identified, its severity is determined using the percentage of FEV_1 loss (for obstructive deficits) or the percentage of FVC loss (for restrictive deficits) [ATS 1991]. Medical followup to determine the nature of any loss in FEV_1 or FVC may include further testing such as TLC, airways resistance, and diffusing capacity.

Similarly, FEV_1/FVC should not be used to determine the severity of the deficit because both FEV_1 and FVC may be decreased—either as a result of a restrictive or a mixed ventilatory defect. Such a pattern of parallel reduction in FVC and FEV_1 has been reported among U.S. and U.K. coal miners [Attfield and Hodous 1992; Soutar and Hurley 1986] (see section 4.2.2 for discussion of epidemiological studies of lung function and respiratory symptoms in coal miners).

The LLN for a spirometric test may be defined as the 5th percentile of the reference population [ATS 1991] (see section 6.5.4 for further discussion). Patterns of restrictive and obstructive ventilatory defects observed with other lung function tests are listed in Table 6-1. Figure 6-1 illustrates determination of FEV_1 and FVC on a spirogram.

6.5.2 Quality Control and Instrumentation

Criteria for improving the accuracy and reproducibility of spirometry test results include the following [ATS 1991]:

- Adherence to ATS guidelines for equipment performance and calibration [ATS 1987a, 1979]
- Maintenance of spirometer temperature between 17° and 40°C to reduce temperature-related errors
- Validation of computer calculations following any changes in hardware or software
- Quality assurance reviews by each laboratory to maintain the precision and accuracy of spirometry measurements, and
- Provision of high-quality of training for technicians (technicians should complete a NIOSH-approved course on spirometry, and laboratories should receive NIOSH certification)

Table 6–1. Characteristics and common causes of restrictive and obstructive ventilatory defects detected from lung function tests

Type of ventilatory defect	Characteristics	Supplemental characteristics	Common causes
Restrictive defect	Decreased VC Relatively normal expiratory flow rate Relatively normal MVV*	Decreased TLC Decreased lung compliance Chronic alveolar hyperventilation Increased (A-a)PO_2 Abnormal distribution of inspired gas Decreased DL_{co}	Interstitial lung disease: Interstitial pneumonitis Fibrosis Pneumoconiosis: Granulomatosis Edema Space-occupying lesions: Tumors Cysts Pleural diseases: Pneumothrorax Hemothorax Pleural effusion, emphysema Fibrothorax Chest-wall diseases: Injury Kyphoscoliosis Spondylitis Neuromuscular disease Extrathoracic conditions: Obesity Peritonitis Ascites Pregnancy

See footnotes at end of table.

(Continued)

Table 6–1 (Continued). Characteristics and common causes of restrictive and obstructive ventilatory defects detected from lung function tests

Type of ventilatory defect	Characteristics	Supplemental characteristics	Common causes
Obstructive defect	Normal or decreased VC Decreased maximum expiratory airflow Decreased MVV	Increased RV Increased airway resistance Abnormal distribution of inspired gas Significant response to bronchodilator Decreased DL_{CO} Decreased lung elastic recoil	Upper airway: Pharyngeal and laryngeal tumors Edema infections Foreign bodies Tumors, collapse, and stenosis of trachea Central and peripheral airway: Bronchitis Bronchiectasis Bronchiolitis Bronchial asthma Parenchymal disease: Emphysema

Source: Gold and Boushey [1988].
*MMV = maximum voluntary ventilation.

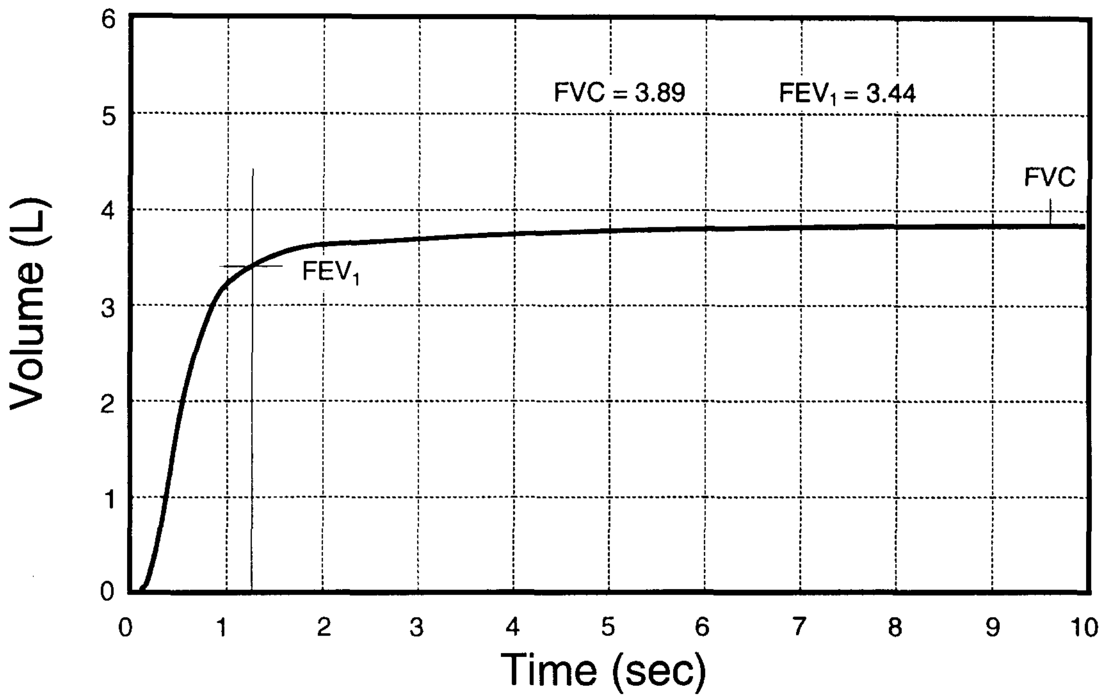

Figure 6–1. FVC and FEV_1 on a normal volume-time curve.

Two basic types of spirometers are available for determining FEV_1, FVC, or FEV_1/FVC: the flow spirometer and the volume spirometer [Hankinson 1993]. The flow spirometer measures the rate at which air is exhaled, and it must integrate flow to determine volume. The volume spirometer collects exhaled air and directly measures volume. A significant advantage of the volume spirometer is its simplicity and direct measurement of volume; a significant disadvantage is that a small error in estimating zero flow can affect the resulting volume, particularly for measurements of FVC [Hankinson 1993]. Further information about quality control, instrumentation, and interpretation of spirometry tests is provided in the ATS reports mentioned above [ATS 1991, 1987a, 1979], in other publications [Hankinson 1993; McKay and Lockey 1992; Harber and Lockey 1992], and in Appendix G of this document. Hankinson et al. [1994] describe a method that uses ceramic flow sensors to estimate body temperature and pressure-saturated (BTPS) correction factors for spirometers.

6.5.3 ATS Acceptability and Reproducibility Criteria for Spirometry Tests

The ATS criteria for acceptability of a spirometry curve is based on the technician's observation that the individual performed the test with a smooth, continuous exhalation, apparent maximal effort, and a satisfactory start—and without coughing, glottis closure, early termination, a leak, or an obstructed mouthpiece [ATS 1987a]. A minimum of three acceptable maneuvers are required according to ATS guidelines [ATS 1987a]. The spirometry testing administered as part of the National Study of Coal Workers' Pneumoconiosis includes five maneuvers, and the maximum FEV_1 and FVC values are used for epidemiological analysis [Attfield and Hodous 1992].

The ATS acceptability and reproducibility criteria are intended to be spirometry testing goals—not criteria for determining the inclusion or exclusion of subjects in an epidemiological study. As shown in two separate studies [Kellie et al. 1987; Eisen et al. 1984, 1983], the ATS reproducibility criteria to determine which subjects should be included in an epidemiological analysis resulted in biased estimates of FEV_1. Eisen [1987] reported that individuals with persistent test failure had twice the annual average rate of FEV_1 decline than those without persistent test failure. Kellie et al. [1987] found that coal miners who failed the reproducibility criteria had a lower mean FEV_1 and significantly more respiratory symptoms (i.e., cough, phlegm, wheeze, and dyspnea) than miners with reproducible tests.

Height has also been shown to affect a person's ability to meet ATS reproducibility criteria (i.e., shorter persons have more difficulty than taller subjects in satisfying ATS reproducibility criteria) [Hankinson and Bang 1991]. The largest FVC and FEV_1 should be reported regardless of the spirometry curve(s) on which they occur [Hankinson 1986; ATS 1987a]. Miller and Scacci [1981] have suggested criteria that can be used to determine whether an individual has used full effort. NIOSH recommends that the ATS acceptability and reproducibility guidelines be used to describe spirometry test results but not to dismiss a finding of abnormality.

6.5.4 Cross-Sectional Spirometry Testing

For spirometry used to assess a person's lung function at one point in time, his or her values for FEV_1, FVC, and FEV_1/FVC are compared with normal reference values for persons of similar gender, age, height, and race. This approach (referred to as cross-sectional spirometry testing) is used to determine whether spirometry test values are within normal limits.

The percentile of the lung function distribution chosen to define the LLN depends on the desired levels of sensitivity and specificity. The 5th percentile has been recommended for use as the LLN in clinical evaluation and diagnosis [ATS 1991].[§] Thus, spirometry values below the 5th percentile are below the expected normal range. Although the use of the 5th percentile as the LLN provides a high degree of specificity (i.e., few false positives), it is implicitly insensitive to detecting early abnormalities, particularly in a healthy population. Greater sensitivity for screening purposes may result from using a higher percentile (e.g., the 10th) as the cutoff point for recommending further medical evaluation or testing [WHO 1995].[**]

NIOSH recommends that the 5th percentile be used to define the LLN for the recommended spirometry tests in the medical screening and surveillance program for coal miners (Appendix E). Miners with a confirmed finding of FEV_1, FVC, or FEV_1/FVC below the LLN are eligible to participate in medical intervention programs (see Section 6.4.4).

NIOSH also recommends that the 10th percentile be used as the cutoff point for recommending further evaluation. Thus, miners with lung function at or below the 10th percentile of the distribution should be advised to seek further clinical evaluation from a qualified health care provider.

[§] The 5th percentile is equivalent to the "normal 95th percentile" used by Knudson et al. [1983].
[**] WHO [1995] uses the terminology from Knudson et al. [1983] (i.e., 90th percentile).

If a miner has respiratory symptoms that suggest an abnormality (whether or not his or her lung function values are below the LLN), he or she may submit medical records and request a review for eligibility to participate in the medical intervention programs.

Spirometry test results that are less than 80% of the predicted values are often used to identify abnormal results, but this criterion has no statistical basis [ATS 1991] and is not recommended. If the data used for deriving the prediction equation are distributed normally (i.e., Gausian distribution) with variability reasonably constant over the age range of interest, then the LLN may be calculated as a defined percentile point of that distribution using the estimated standard error. However, this approach is not recommended because assumptions of normality and homogeneity of variance are rarely met in actual spirometric surveys of adults [Knudson et al. 1983]. Instead, Knudson et al. [1983] advise determining the LLN as a defined lower percentile point of the actual distribution of data.

The Knudson et al. [1983] equations are recommended as the basis for the normal reference values for spirometry tests (i.e., the LLN for FEV_1, FVC, and FEV_1/FVC) of U.S. coal miners for the following reasons:

- The analyses described by Knudson et al. [1983] meet the methodological, epidemiological, and statistical criteria recommended by the ATS [1991] for the selection of reference values.

- The estimate of the age-related decline in FEV_1 found by Knudson et al. [1983] is very similar to that reported by Attfield and Hodous [1992] for nonsmoking coal miners.

- The Knudson et al. [1983] data are based on cross-sectional studies of lifetime nonsmokers; thus, the spirometry test results will be applicable to the respiratory health surveillance of miners as a group and to the medical evaluation of individual miners for diagnosis and other clinical purposes.

As additional data become available, NIOSH may update these recommendations for reference values in spirometry testing. In particular, future studies may provide reference values for several ethnic groups that are not currently available in the literature.

6.5.5 Longitudinal Spirometry Testing

Longitudinal spirometry used in medical screening allows comparisons of a worker's preplacement lung function values with those determined in later spirometric examinations. Such periodic spirometry testing may be useful for early identification of a worker with excessive loss of lung function (i.e., before the loss is apparent from cross-sectional testing) [Hankinson and Wagner 1993]. This identification is possible because workers as a group are often healthier than the general population and have above-average lung function [Becklake and White 1993]. Thus, comparing a worker's lung function values with general population reference values may not detect an actual loss in that worker's lung function [Hankinson and Wagner 1993]. About half of a worker population may benefit from longitudinal (in addition to cross-sectional) evaluation of spirometry [Hankinson and Wagner 1993].

Hankinson and Wagner [1993] recommend establishing a baseline FEV_1 value for each worker from several initial spirometric examinations. They then recommend calculating the longitudinal LLN by taking 85 percent of this baseline value minus the expected decline over a period of time (based on the individual's age).

6.5.6 Additional Medical Tests of Lung Function

Additional lung function tests may be required for further evaluation of miners with abnormal spirometric examinations or with respiratory symptoms. Such tests may be too complicated or expensive to administer during routine screening, or they may have large variability within a normal population [Miller and Scacci 1981; Hankinson 1986; WHO 1995].

Recommended methods are available for measuring the diffusing capacity of the lung for carbon monoxide (DLCO) [Ferris 1978] and for calculating predicted values [Crapo and Morris 1981]. Changes in the membrane-diffusing capacity or in the capillary volume that are caused by structural lung damage can influence the diffusing capacity of the lung [Miller and Scacci 1981]. The single-breath method of measuring DLCO is the most widely used and best standardized method of measuring diffusing capacity [Gold and Boushey 1988; Hankinson 1986]. Because DLCO can be abnormal in numerous respiratory disorders, the test lacks specificity for work-related respiratory diseases. Also, cigarette smoking has been associated with reduced DLCO (because of elevated carboxyhemoglobin) and should be considered in the diagnosis [Hankinson 1986]. Measuring the DLCO is indicated when other tests such as spirometry do not show sufficient lung impairment to explain a patient's respiratory symptoms [Hankinson 1986; Miller and Scacci 1981].

6.6 OTHER ISSUES PERTAINING TO RECOMMENDATIONS FOR MEDICAL SCREENING AND SURVEILLANCE

6.6.1 Evaluating the Work-Relatedness of COPD Among Coal Miners

The evidence implicating exposure to coal mine dust as a cause of COPD in coal miners has been reviewed in Chapter 4 and is used in Chapter 7 as part of the basis for the NIOSH REL for respirable coal mine dust. Becklake [1985] concluded that the causal link between occupational exposure and chronic airflow limitation among coal miners has been demonstrated "beyond reasonable doubt." Becklake's conclusion refers to the epidemiological evidence from studies of exposures and responses in groups of miners. In these studies [Attfield and Hodous 1992; Seixas et al. 1993, 1992; Marine et al. 1988; Soutar et al. 1988; Soutar and Hurley 1986; Rogan et al. 1973], the variability among individuals' lung function responses to similar exposures implies that a certain proportion of miners will respond either more or less severely than the average. Among miners who respond more severely than the average, some may have clinically significant reductions in lung function, as shown by Marine et al. [1988]. Soutar and Hurley [1986] found that studies limited to working miners may underestimate the clinical importance of dust-associated reductions in lung function. Hurley and Soutar [1986] identified a subgroup of coal miners (including those who had left the industry voluntarily before normal retirement age) for whom the average effect of dust exposure on reduction in FEV_1 was more than twice that reported by Marine et al. [1988].

The findings of these epidemiological studies indicate that exposure to coal mine dust may lead to clinically significant COPD. But as Becklake [1985] notes, it is unlikely that medical evidence could provide scientific proof of the work-relatedness of a particular case of COPD, even though "a reasonable statement of probability" may often be obtained. Kusnetz and Hutchinson [1979] identified the various elements that need to be considered when physicians attempt to make such an individual assessment of probability:

- Verification of convincing epidemiological evidence that occupational exposure may cause COPD
- Clinical evidence that the disease exists in the individual concerned
- Evidence that there has been an exposure of sufficient degree or duration to result in disease
- An assessment of other relevant factors such as nonoccupational exposures that might cause COPD or other special circumstances.

The spirometric examinations and questionnaires on respiratory symptoms and work history (which are included in the recommended medical screening and surveillance program for coal miners) will provide important information for effective workplace surveillance, medical diagnoses, and individual advice to miners.

6.6.2 Medical Intervention Strategies

The risk of developing PMF increases with increasing initial category of simple CWP [Attfield and Seixas 1995; Attfield and Morring 1992b; Hurley and Maclaren 1987; Hurley et al. 1987; McLintock et al. 1971; Cochrane 1962]. Furthermore, the risk of progression to a higher category of simple CWP increases with increasing intensity of exposure (mean dust concentration) [Jacobsen et al. 1970, 1971] and increasing cumulative exposure (i.e., intensity × duration) [Jacobsen 1973, 1979]. Thus, the risk of PMF increases systematically both with initial category of simple CWP and with the amount of progression (over 5-year periods) from each initial category (including categories 0/0, 0/1, and 1/0) [McLintock et al. 1971]. The amount of time spent in a disease category of simple CWP may also influence the risk of progression to a higher category [Morfeld et al. 1992].

The weight of evidence from these studies suggests that a reduction in worker exposures to respirable coal mine dust will decrease the risk of simple CWP progression and thus the risk of PMF. However, other factors may influence the effectiveness of dust reduction in decreasing the risk of disease progression. Cumulative exposure and residence time of dust in the lungs may be important factors in the development of PMF [Maclaren et al. 1989; Hurley et al. 1987]. Maclaren and Soutar [1985] found that 32% of the miners who developed PMF after they left mining had no evidence of CWP (i.e., category 0) when they terminated their employment in mining. The effectiveness of dust reduction may also depend on the magnitude of that reduction. Hurley and Maclaren [1987] estimated that just 1 in 10,000 cases of PMF would be prevented if all miners who had developed simple CWP category 1/0 or greater at a mean concentration of 2.0 mg/m^3 of respirable coal mine dust were then allowed to work at a mean concentration of 1.0 mg/m^3. However, the same report also shows that reducing average dust concentrations from 2 to 1 mg/m^3 over a 40-year working lifetime would more than halve the risk of PMF—from between 7 and 18 cases per 1,000, to between 3 and 7 cases per 1,000, depending on coal rank [Hurley and Maclaren 1987].

The effectiveness of reducing exposures to respirable coal mine dust has not been adequately studied with regard to reversing or reducing lung function deficits. However, some evidence shows that reduction or cessation of smoking can at least partially reverse the functional abnormalities associated with smoking [McCarthy et al. 1976] and the structural changes in the peripheral airways of asymptomatic young smokers [Ingram and O'Cain 1971]. These studies of smoking suggest that reducing or ceasing exposures to other contaminants associated with airways obstruction and loss of lung function (e.g., respirable coal mine dust and respirable crystalline silica) may also effectively reverse or further reduce adverse effects. NIOSH therefore recommends, as a prudent public health measure, that miners be permitted to work in a low-dust environment if they have evidence of COPD caused or exacerbated by exposure to coal mine dust.

Further research is needed to evaluate the effectiveness of medical interventions such as reducing or ceasing exposures to respirable coal mine dust or respirable crystalline silica. Any analysis of the effectiveness of the transfer program would need to consider possible bias from the low rate of participation: only 23% of eligible coal miners (2,119 of 9,138 miners) elected to participate [Wagner and Spieler 1990]. Goldenhar and Schulte [1994] have described additional methodological issues in intervention research.

A related research need is to evaluate the availability of mine areas where exposures to respirable coal mine dust and respirable crystalline silica are as far below the respective RELs as feasible. The tables in Appendix B show that mean concentrations for most occupations have been below the PEL of 1 mg/m^3 for miners transferred under 30 CFR 90. However, the mean concentrations for some occupations (e.g., roof bolter and continuous miner helper) exceed the PEL of 1 mg/m^3, and a substantial percentage of samples show measured concentrations greater than 1 mg/m^3. Limited data from sampling required for miners transferred under 30 CFR 90 also show that concentrations of respirable crystalline silica exceeded the NIOSH REL and the MSHA PEL for some occupations. NIOSH advocates primary prevention (through reducing exposures) rather than secondary intervention as the most effective means of eliminating occupational diseases.